DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Fx Solutions
Ms. Cheryl Hastings
1663 Rue De Majornas
01440 Viriat
FRANCE

November 13, 2015

Re: K150488
Trade/Device Name: Humelock II Reversible Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX
Dated: October 14, 2015
Received: October 15, 2015

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150488

Device Name: Humelock II Reversible Shoulder System

Indications for Use:

The Humelock II Reversible Shoulder System is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stems are intended for cemented or cementless use. The metaglene baseplate is intended for cementless use with the addition of screws for fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ **(**21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Prepared:	October 14, 2015
Submitter:	Fx Solutions 1663 Rue de Majornas Viriat, France 01440
Contact:	Jean-Jacques Martin +33 4 74 55 35 55 www.fxsolutions.fr
Proprietary Name:	Humelock II Reversible Shoulder System
Common Name:	Reverse Shoulder Prosthesis
	Classification Names: 21 CFR 888.3660: Shoulder joint metal/polymer semi- constrained cemented prosthesis; Class II
Product Codes:	PHX
Substantially Equivalent Devices:	Zimmer Anatomical Shoulder Inverse/Reverse Total Shoulder Prosthesis, K053274 Fx Solutions Humelock II Cemented Shoulder System, K123814, K140071 Fx Solutions Humelock II Cementless Shoulder System, K130759

Device Description:

Tornier Aequalis Reversed II Shoulder System, K132285

The Humelock II Reversible Shoulder is a total shoulder prosthesis designed for use in patients with a non-functional rotator cuff. The components of the system include a glenoid baseplate, standard and locking bone screws, optional baseplate post extensions, centered and eccentric glenospheres with and without a stabilization screw, 135/145º humeral cups, standard humeral cups and a 135/145º adaptor. These components are intended for use with the previously cleared Humelock II Cemented Humeral Stems and the Humelock II Cementless Humeral Stems. The design of the Humelock II Reversible Shoulder allows conversion from an anatomic shoulder configuration to a reverse shoulder configuration either intraoperatively or during revision of an anatomic shoulder with a well fixed humeral stem.

The glenoid baseplate, standard and locking screws, baseplate post extensions, glenosphere screws and 135/145° reverse adapters are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. The backside of the baseplate and the post extensions are coated with a plasma sprayed CP Titanium and Hydroxylapatite coating. The glenospheres are manufactured from Co-Cr-Mo conforming to ISO 5832-12. The 135/145° Humeral Cups and standard Humeral Cups are manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and UHMWPE conforming to ISO 5834-1 and ISO 5834-2.

Intended Use / Indications:

The Humelock II Reversible Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stems are intended for cemented or cementless use. The metaglene baseplate is intended for cementless use with the addition of screws for fixation.

Summary of Technologies/Substantial Equivalence:

The Humelock II Reversible Shoulder is substantially equivalent to the predicate devices in regards to its intended use and indications, materials, design and sizes. Differences between the subject device systems and the predicate device systems do not raise new types of safety and effectiveness questions.

Non-Clinical Testing:

Range of motion analysis, construct fatigue testing, testing of the glenosphere / baseplate connection and testing of the glenoid baseplate stability were conducted. The results of these tests indicate that the performance of the Humelock II Reversible Shoulder is adequate for its intended use.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence of the Humelock II Reversible Shoulder to the predicate devices.